

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”) (collectively the “United States”); and Smith & Nephew, Inc., on behalf of its Orthopedic Reconstruction Global Business Unit (hereinafter referred to as “Smith & Nephew”) (hereinafter, all of the above, collectively referred to as “the Parties”), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

- A. Smith & Nephew plc is a publicly traded British corporation headquartered in London, England. Smith & Nephew, Inc., is a wholly owned subsidiary of Smith & Nephew plc, with a place of business in Memphis, Tennessee. Smith & Nephew manufactures and distributes orthopaedic medical devices.
- B. The United States contends that Smith & Nephew submitted or caused to be submitted improper claims for payment to the Medicare Program (“Medicare”), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh.
- C. The United States contends that it has certain civil claims, against Smith & Nephew, as specified in Section III, Paragraph 5, below, for engaging in the following conduct during the period from January 1, 2002 to December 31, 2006 (hereinafter the “Covered Conduct”):

Smith & Nephew used various forms of financial arrangements to induce orthopaedic surgeons to cause providers to use Smith & Nephew's hip and knee joint replacement implants in order to maintain and increase Smith & Nephew's market share. These financial arrangements came in the form of fee-for-service contracts, fixed fee contracts, and product development contracts, among others. The United States contends that certain of these financial arrangements were improper, that the remuneration paid thereunder was improper and/or unlawful, and that these arrangements caused hospitals and physicians to submit false and fraudulent claims for replacement of hip and knee joints using Smith & Nephew implants to Medicare.

D. The United States contends also that it has certain administrative claims, as specified in Section III, Paragraph 6, below, against Smith & Nephew for engaging in the Covered Conduct.

E. Smith & Nephew denies that it engaged in any wrongdoing and specifically denies that any of the payments, services, or remuneration were illegal, improper, or resulted in any false or fraudulent claims.

F. This Agreement is neither an admission of liability by Smith & Nephew nor a concession by the United States that its claims are not well founded.

G. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties mutually desire to reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

NOW THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Smith & Nephew agrees to pay to the United States \$28,929,840 (TWENTY-EIGHT MILLION, NINE HUNDRED AND TWENTY-NINE THOUSAND, EIGHT HUNDRED AND FORTY dollars) (the "Settlement Amount"). Smith & Nephew agrees to pay the Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of New Jersey. Smith & Nephew shall make this electronic funds transfer no later than four o'clock in the afternoon (4:00 p.m.) EST on September 28, 2007.

2. Smith & Nephew has executed contemporaneously with this Agreement, a Deferred Prosecution Agreement ("DPA") with the United States which is annexed hereto as Exhibit A and incorporated herein by reference.

3. Default. In the event that Smith & Nephew breaches the terms of this Agreement or the DPA (as defined in Paragraph 51 of the DPA), Smith & Nephew shall be in Default of its obligations under this Agreement ("Default"). The United States will provide written notice of the Default, and Smith & Nephew shall have an opportunity to cure such Default within fourteen (14) days from the date of receipt of the notice. Notice of Default will be delivered to counsel for Smith & Nephew, or to such other representative as Smith & Nephew shall designate in advance in writing.

4. Exclusion. In the event a Default is not cured within the fourteen (14) day period specified in Paragraph 3, above, the OIG-HHS may exclude Smith & Nephew from participating in all Federal health care programs. Such exclusion shall have national effect and shall also apply to all other federal procurement and nonprocurement programs. Federal health care programs shall not pay anyone for services, including administrative and management services, or items manufactured, furnished, or distributed by Smith & Nephew in any capacity while Smith & Nephew is excluded. This payment prohibition applies to Smith & Nephew and all other individuals and entities (including, for example, anyone who employs or contracts with Smith & Nephew, and any hospital or other provider where Smith & Nephew provides services). The exclusion applies regardless of who submits the claim or other request for payment. Smith & Nephew shall not submit or cause to be submitted to any Federal health care program any claim or request for payment for services or items manufactured, furnished, or distributed by Smith & Nephew during the exclusion. Violation of the conditions of the exclusion may result in criminal prosecution, the imposition of civil monetary penalties and assessments, and an additional period of exclusion. Smith & Nephew further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for services or items manufactured, furnished or distributed to such providers, beneficiaries or sponsors after the effective date of the exclusion. Smith & Nephew waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion Smith & Nephew wishes to apply for reinstatement, Smith & Nephew must submit a written request for reinstatement to the

OIG in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Smith & Nephew will not be reinstated unless and until the OIG approves such request for reinstatement.

5. Subject to the exceptions in Paragraph 7, below, in consideration of the obligations of Smith & Nephew set forth in this Agreement, conditioned upon Smith & Nephew's full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Smith & Nephew together with its current and former parent corporations; each of its direct and indirect subsidiaries; brother or sister corporations; divisions; current or former owners, officers, directors, and affiliates; and the predecessors, successors and assigns of any of them from any civil or administrative monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Anti-kickback Act, 41 U.S.C. § 55; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; and any statutory provision applicable to the federally-funded programs in this Agreement for which the Civil Division, United States Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, § 0.45(d); and common law claims including payment by mistake, unjust enrichment, and disgorgement or fraud, breach of contract and recoupment for the Covered Conduct.

6. In consideration of the obligations of Smith & Nephew set forth in this Agreement and in the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Smith & Nephew, and conditioned upon Smith & Nephew's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative claim or action seeking exclusion from Medicare, Medicaid, and other Federal

health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Smith & Nephew, together with its current and former parent corporations; each of its direct and indirect subsidiaries; brother or sister corporations; divisions; current or former owners, officers, directors, and affiliates; and the predecessors, successors and assigns of any of them, under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7, below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Smith & Nephew, together with its current and former parent corporations; each of its direct and indirect subsidiaries; brother or sister corporations; divisions; current or former owners, officers, directors, and affiliates; and the predecessors, successors and assigns of any of them, from Medicare, Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Smith & Nephew) are the following:

- a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;

- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon such obligations as are created by this Agreement;
- f. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability of individuals, including officers and employees; and
- i. Any liability for express or implied warranty claims or other claims for defective or deficient products or services.

8. Smith & Nephew waives and shall not assert any defenses Smith & Nephew may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. Smith & Nephew, together with its current and former parent corporations; each of its direct and indirect subsidiaries; brother or sister corporations; divisions; current or former owners, officers, directors, and affiliates; and the predecessors, successors and assigns of any of them, fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Smith & Nephew, together with its current and former parent corporations; each of its direct and indirect subsidiaries; brother or sister corporations; divisions; current or former owners, officers, directors, and affiliates; and the successors and assigns of any of them, has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and, if applicable, Smith & Nephew agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

11. Smith & Nephew agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Smith & Nephew, together with its current and former parent corporations; each of its direct and indirect

subsidiaries; brother or sister corporations; divisions; current or former owners, officers, directors, employees, shareholders, agents, and affiliates; and the predecessors, successors and assigns of any of them in connection with the following shall be “unallowable costs” on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):

(1) the matters covered by this Agreement and any related plea or deferred prosecution agreement;

(2) the United States’ audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) Smith & Nephew’s investigation, defense, and corrective actions undertaken in response to the United States’ audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement and any plea or deferred prosecution agreement;

(5) the payment Smith & Nephew makes to the United States pursuant to this Agreement, including any costs and attorneys fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to:

(i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and

(ii) prepare and submit reports to the OIG-HHS.

However, nothing in this Paragraph 11.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Smith & Nephew. (All costs described or set forth in this Paragraph 11.a. are hereafter “unallowable costs.”)

b. Future Treatment of Unallowable Costs: If applicable, these unallowable costs shall be separately determined and accounted for by Smith & Nephew, and Smith & Nephew shall not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Smith & Nephew or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Smith & Nephew further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Smith & Nephew or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Smith & Nephew agrees that the United States, at a minimum, shall be entitled to recoup from Smith & Nephew any overpayment

plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Smith & Nephew or any of its subsidiaries or affiliates on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Smith & Nephew or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 5, 6 and 13.

13. Smith & Nephew waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

14. Smith & Nephew warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following its payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a

contemporaneous exchange for new value given to Smith & Nephew, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Smith & Nephew was or became indebted, on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

15. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. Smith & Nephew represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

17. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the District of New Jersey, except that disputes arising under the DPA and/or CIA shall be resolved exclusively under the dispute resolution provisions in those agreements.

18. This Agreement and any other agreement incorporated herein by reference, constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties, except that only the OIG-HHS and Smith & Nephew must agree in writing to a modification of the terms of the CIA.

19. The individuals signing this Agreement on behalf of Smith & Nephew represent and warrant that they are authorized by Smith & Nephew to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

20. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

21. This Agreement is binding on Smith & Nephew's successors, transferees, heirs, and assigns.


22. This Agreement is effective on the later of (1) the date of signature of the last signatory to the Agreement; or (2) the date the Court approves the DPA ("Effective Date" of the Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[SIGNATURE BLOCKS ON FOLLOWING PAGE].

THE UNITED STATES OF AMERICA

DATED: 9-27-07

BY: _____


CHRISTOPHER J. CHRISTIE
United States Attorney
District of New Jersey

DATED: _____

BY: _____


GREGORY E. DEMSKE
Assistant Inspector General for
Legal Affairs
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department of
Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
CHRISTOPHER J. CHRISTIE
United States Attorney
District of New Jersey

DATED: 9/27/97

BY: 

GREGORY E. DEMSKE
Assistant Inspector General for
Legal Affairs
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department of
Health and Human Services

SMITH & NEPHEW, INC.DATED: 9/27/07BY: 

Name:

Title:

NIXON PEABODY LLP

100 Summer Street

Boston, Massachusetts 02110-2131

(617) 345-1323

DATED: _____

BY: _____

MELISSA TEARNEY, ESQ.

DAVID A. VICINAZO, ESQ.

Counsel for Smith & Nephew, Inc.

SMITH & NEPHEW, INC.

DATED: _____

BY: _____

Name:

Title:

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DATED: 9/27/07

BY: David Vicinazo DDP
Melissa P. Tearney DDP

MELISSA TEARNEY, ESQ.

DAVID A. VICINAZO, ESQ.

Counsel for Smith & Nephew, Inc.

